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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,247	11/15/2001	Gary K. Michelson	101.0083-00000	4911
22882	7590	01/30/2004	EXAMINER	
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER

3738

DATE MAILED: 01/30/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/991,247

Applicant(s)

MICHELSON, GARY K.

Examiner

Paul B. Prebilib

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other: \_\_\_\_\_

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The 35 USC 112, first paragraph rejection of claim 17 has been withdrawn as a result of Applicant's persuasive response. In addition, the other grounds of rejection have been withdrawn because amendments rendered them moot.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-28, 56-59, and 85-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original support for the open ended range of openings for instrument engagement as claimed. In fact, the maximum disclosed number is four; see the paragraph bridging pages 13 and 14. In particular, there is no original support the open ended range of at least one or at least three as presently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 3, and 5-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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With regard to claims 1, 2, 3, and 5-28, the new language, of claim 1, does not have clear antecedent support from the specification such that it is unclear what features of the disclosed invention are being claimed. Claims 2, 3, and 5-28 are dependent upon claim 1, and thus, they have the same antecedent basis problem.

With regard to claims 29-59, the description of the "body" and the mid-longitudinal axis, in claim 29, does not have clear antecedent support or basis from the specification such that it is unclear what features of the disclosed invention are being claimed. Claims 30-59 contain the claim language of claim 29 because they depend therefrom such that they also have the same antecedent support problem.

It is well settled that the claims should have at least clear implicit support from specification and not merely from the original claims. Yet, upon review of page 12 of the response filed November 14, 2003, it is clear that the Applicant is relying on the original claims to show that the present claims have support. For this reason, the Applicant is respectfully requested to review the claims of record and amend the specification such that there is antecedent basis therein for all the claimed subject matter. This is of course assuming that there was original support for the subject matter in the original specification or claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-16, 18, 23-49, 55-78, and 84-88 are rejected under 35 U.S.C.

103(a) as being unpatentable over Michelson (US 5,860,973) in view of Boyce et al (US 6,294,187). Michelson discloses a body (400) with upper (402) and lower (404) portions and side (406) portions. Michelson also has projections or ratchetings (220, 420) and openings (428) as claimed; see Figure 10, Figure 8, column 8, lines 47-61, column 5, line 57 to column 6, line 5, and column 7, lines 46-59. Michelson lacks a composite of cortical bone and bioresorbable material as claimed. However, Boyce discloses that such materials were known; see column 11, line 65 to column 12, line 9, column 14, lines 33-335 and column 7, line 55 to column 8, line 39. Therefore, it is the Examiner's position that it would have been considered prima facie obvious to an ordinary artisan to make the Michelson implant out of the cortical bone/bioresorbable material composite of Boyce for the same reasons that Boyce does the same; see column 1, line 56 to column 2, line 4 of Boyce.

With regard to claim 8, Michelson fails to disclose the dimensions as set forth in the claim. However, the mere recitation of size or proportion is considered prima facie obvious over the structure set forth in Michelson because there is no clear indication that such size or proportion is for some particular purpose, performs some unexpected function, or has some unobvious characteristics. MPEP 2144.04 states:

*In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

With regard to claim 23, Michelson discloses round openings but lacks oval openings as claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use oval openings because Applicants have not disclosed that oval openings provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well with a "generally oval-shaped" opening as compared to a round opening. Therefore, it would have been an obvious matter of design choice to modify Michelson to obtain the invention as specified in the claims.

With regard to claims 26-28, Michelson discloses one instrument opening in each end but lacks at least one or three openings as claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have additional openings because Applicants have not disclosed that additional provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the instruments could be used in a serial fashion instead of at the same time as in the structure. Therefore, it would have been an obvious matter of design choice to modify Michelson to obtain the invention as specified in the claims.

Claims 17, 50, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson and Boyce et al as applied to claims 1-3, 5-16, 18, 23-49,, 55-78, and 84-88 above, and further in view of Boyce et al (US 5,899,939). Michelson

fails to disclose the use of a scar-inhibiting material with the implant as claimed.

However, Boyce discloses that it was known to coat many types of medically/surgically useful substances onto similar vertebral implants; see column 4, line 53 to column 5, line 32. Therefore it is the Examiner's position that it would have been obvious to coat the Michelson device with any useful substance, including scar-inhibiting materials, since there has been no showing of criticality for using such a substance in the same environment as Michelson.

Claims 19-22, 51-54, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson and Boyce et al as applied to claims 1-3, 5-16, 18, 23-49, 55-78, and 84-88 above, and further in view of Michelson (US 5,484,437). Michelson fails to disclose the use of a drill, mill, or hollow tube instrument with the implant thereof. However, Michelson teaches that it was known to use a hollow insertion tube, drill, and mill with similar spinal implant systems; see Figure 11A and column 21, line 54 to column 22, line 22. Therefore, it is the Examiner's position that it would have been considered prima facie obvious to include a hollow insertion tube, drill and mill to the Michelson device in order to prepare the Michelson ('973) implant for implantation.

### ***Response to Arguments***

The arguments filed with the November 14, 2003 response were considered but found to be moot in view of the new grounds of rejections.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.



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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
Art Unit 3738